



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/075,615

02/15/2002

Joseph C. Cauthen III

8442.0002-02

2841

22852

7590

04/01/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/075,615	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,7 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,7 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/18/2008, 6/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 2-4, 7, 17-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-4, 7, 17 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear what the centralized vertical "dimension" refers to; since this feature is not described in the specification or drawings, it is considered to be new matter. Examiner suggests changing the term "dimension" in claim 21 lines 8 and 9 to ----extension---- as described in the specification and drawings. Claim 3, "dimension" in line 5; claim 7, "dimension" in line 3; and claim 17 "dimension" in line 3, are rejected for the same reason as above.
4. Claim 21 further includes the limitation lateral "portion" in line 10. It is unclear what the lateral portion refers to; since this feature is not described in the specification or drawings, it is considered to be new matter. Examiner suggests changing the term "portion" in claim 21 line 10 to ----extension--- as described in the specification and

Art Unit: 3774

drawings. Claim 2 line 3, claim 3 line 3, claim 4 line 2 all include the term "portion" and are rejected for the same reason as above.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a plane has a cross sectional shape.

Examiner suggests amending the claim to define that the vertical ---extension--- has a cross-sectional shape, since the shape of a reference plane (cross-sectional or not) is arbitrarily assigned.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

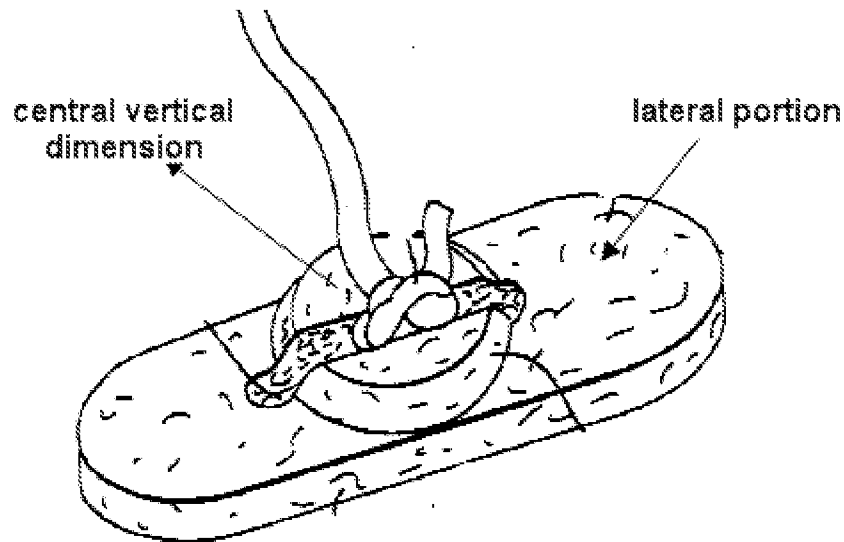
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2-4, 7, and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (U.S. Pat. No.: 5,545,178).

9. With respect to independent claim 21, Kensey discloses a therapeutic treatment device 106 comprising a biocompatible material for placement in and across an aperture (see fig. 20) such that the material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair (col. 8 lines 21-31, also col. 13 lines

Art Unit: 3774

25-42). The device has means for acute securement of the device (see fig. 20). The device comprises an elongated centralized vertical dimension (at 106D, fig. 17), the vertical dimension having a horizontal axis and a left and a right lateral portion (on either side of the vertical dimension, see fig. 14), as depicted below.

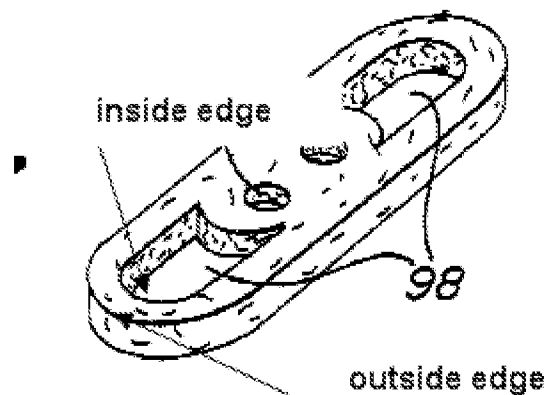


10. Examiner is considering the limitation “a therapeutic or prophylactic intervertebral disc wall treatment device for placement in and across an aperture in the intervertebral disc wall” in applicants’ preamble to be a recitation of the intended use of the claimed device. The recited intended use does not result in a structural difference between the claimed invention and the prior art (see MPEP 2111.02 and 2114).

11. Furthermore, the device of Kensey is fully capable of performing the function of “placement in and across an aperture in the intervertebral disc wall”, since Kensey discloses the use of the device as a closure for arthroscopic (joint surgery, including spinal procedures) or other minimally invasive surgical procedures (col. 5 lines 25-33).

Art Unit: 3774

12. With respect to claim 2, the lateral portions comprise surfaces residing in planes. The left and right lateral portions each form an angle of about 0-60 degrees below a reference plane orthogonal to the central vertical dimension (see fig. 20, angle of about 0). The left and right lateral portions comprise an inside edge which is shorter than the length of an outside edge (see fig. 27, annotated below).



13. With respect to claim 7, the device further comprises a recess (96 or 98, see figs. 26-28 for example). Each surface lies adjacent to the centralized vertical dimension (By virtue of being on the same device).

14. The centralized vertical dimension lies in a plane having a curved cross sectional shape (see fig. 28). The device is made of bioresorbable material (col. 8 lines 60-63). The device can alternatively comprise a biocompatible fiber mesh (col. 8 lines 27-37). The therapeutic device comprises a material to facilitate regeneration of disc tissue (collagen, col. 8 line 25 or bio-active agent, col. 18 line 44-48).

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3774

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774